

PATENT

**APPLICATION FOR
UNITED STATES LETTERS PATENT**

for

A Weight Management System for Obese Animals

by

Linh Bui, Tiffany Bierer and Michael Wilson

10549-604501

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[0001] The invention generally relates to a pet food for use in a weight management system for companion animals. More particularly, the weight management system includes a high protein, low caloric daily diet that includes a functional ingredient that further modulates metabolism and build lean muscle mass in companion animals.

RELATED ART

[0002] In westernized societies the most prevalent form of malnutrition in humans is over-consumption of calories resulting in excess body fat. Studies have shown that approximately 20-30% of dog and cat populations are overweight and obese (over-fat). Obesity in domesticated dogs and cats has been linked to the development of numerous diseases including renal failure, diabetes, arthritis and thyroid dysfunction. Overweight dogs have an increased risk of developing transitional cell carcinoma of the bladder. Further, it is well established that obesity is a predisposing factor to idiopathic hepatic lipidosis in cats, however, their inability to convert dietary C18 essential fatty acids into long chain fatty acids creates a need for dietary consumption of 20 carbon long chain fatty acids. Such a dietary requirement leaves cats extremely vulnerable to weight disorders and weight-associated diseases such as diabetes (Appleton *et al.*, 2000).

[0003] Obesity generally is considered present when body weight of the companion pet is 15% or more greater than optimum, which is the point at which health problems begin increasing with increasing weight. Generally speaking, the incidence of obesity in domestic animals increases with age. Similar to humans, as a dog ages, body fat increases, and lean body mass decreases. However, obesity commonly goes unnoticed by the animal's owner and, thus, poses a life-threatening problem to domesticated animals.

[0004] Some pet food compositions formulated to prevent or treat obesity in animals have been described. U.S. Patent 6,071,544 teaches that a specific combination of long chain conjugated fatty acids (0.2 to 1.5 weight % of dry matter) together with up to 50% protein promotes weight loss in cats. A diet greater than

about 16% by weight of animal-based protein is taught to reduce body fat in geriatric dogs (WO 00/51443). However, U.S. Patent 5,141,755 teaches that non-meat based animal fats in a high protein, high farinaceous diet provides an ovo or lacto-ovo nutritionally balanced pet food product. U.S. Patent 4,892,748 describes a low calorie dog treat that is comprised primarily of cellulose, a β -1,4-glucan that affords no nutritional value to the animal.

[0005] Similarly, diets disclosed for the treatment of human obesity have included compositions such as a concentrate that consists entirely of non-animal natural components, a lack of simple sugars and a flour comprising at least 50% protein, less than 15 % carbohydrates and 35 to 50% plant fiber for use in the preparation of foods such as bakery products (U.S. Patent 4,737,364; EP 965278 A1). Such diets are not completely without credence because hypertension, and thus risk of developing cardiovascular disease, in obese patients have been linked to disturbances in carbohydrate metabolism (Nobels *et al.*, 1989).

[0006] However, low caloric diets comprising increased ratios of amino acids to carbohydrates, such as the diet taught in U.S. Patent 4,009,265, cause increased blood urea concentrations. Urea is a by-product of protein or amino acid catabolism and thus is directly related to the amount of protein in a diet. The kidneys function to remove urea from the plasma, and in this regard high protein diets place an unusual burden on the kidneys which can lead to severe consequences over time including developing azotemia or uremia.

[0007] Also symptomatic of high protein diets is the potential to induce ketosis, a condition that is shared in humans and dogs. Ketosis is a pathological condition in which the brain consumes ketone bodies as its major fuel source and is a diagnostic for diabetes mellitus. For example, urine abnormally high in ketone bodies is expected after a prolonged fast. However, this metabolic shift is undesirable and also leads to severe renal damage if experienced over long periods of time.

[0008] Natural products derived from plants and food have frequently been the source of effective drugs, and in recent years there has been an increased interest in the analysis of these natural products, especially where a clinical benefit is claimed. For this reason, functional ingredients are often added to pet foods in order to effect a particular metabolic response. For example, EP 646325A1 describes a pet food comprised of at least 30% by weight of indigestible dextrin that demonstrates obese-

improving effects by controlling blood-sugar levels and insulin secretion in dogs and cats.

[0009] U.S. Patent 5,962,043 teaches jojoba seed meal as a nutritional supplement in animal feed, especially companion dogs, to promote weight loss. Simmondsin is described as the active or functional ingredient, that based on previous research, results in an associated reduction in food intake and retardation of growth. These formulations include high fat and high caloric density to ensure palatability.

[0010] U.S. Patent 6,204,291 teaches dietary supplementation with L-carnitine, a naturally occurring acid also known as β -Hydroxy- γ -trimethylaminobutyrate, to dog food to promote weight loss. Carnitine is found in the body and is enzymatically combined with fatty acids to facilitate their transportation through mitochondrial membranes, thus aiding in fatty acid metabolism (Yalkowsky, S.H., 1970). Oral administration of L-carnitine for obesity in mammals has been described in U.S. Patent 3,810,994. It also has been implicated in improvements in myocardial contractility and systolic rhythm in congestive heart failure, it has been administered in cases of cardiac arrhythmia (U.S. Patent 3,830,931; U.S. Patent 3,968,241), and it has been used for increasing the level of high density lipoproteins (U.S. Patent 4,255,449).

[0011] Prior to the present invention, current solutions have not provided a comprehensive approach in addressing the issues of weight management. Most diets simply lower caloric density, increase total carbohydrates by increasing fiber which leads to reduced palatability, thereby creating a diet that leaves the animal hungry and, sometimes, induces lean muscle loss.

[0012] The present invention provides a long-sought after weight management system for companion animals, and in particular obese animals, for treating and preventing obesity through dietary intervention in companion animals such as dogs and cats. The present invention also increases the lean body mass of companion animals as well as enhancing the satiety and decreasing voluntary food intake of an animal.

SUMMARY OF THE INVENTION

[0013] The present invention provides a comprehensive weight management system to help optimize the body composition of a domestic animal through dietary intervention by providing a pet food product comprising about 35 to about 70% by

weight of a protein, about 4 to about 10% by weight of a fat, about 5 to about 25% by weight of a fiber, about 10 to about 35% by weight of a digestible carbohydrate, and about 0.1 to about 1% by weight of a functional ingredient.

[0014] An additional object of the invention is a process for producing a pet food product that provides comprehensive weight management in companion animals by adding about 35 to about 70% by weight of a protein, about 4 to about 10% by weight of a fat, about 5 to about 25% by weight of a fiber, about 10 to about 35% by weight of a digestible carbohydrate, and about 0.1 to about 1% by weight of a functional ingredient.

[0015] A further object of the present invention is a process of feeding companion animals a pet food product that provides comprehensive weight management by comprising about 35 to about 70% by weight of a protein, about 4 to about 10% by weight of a fat, about 5 to about 25% by weight of a fiber, about 10 to about 35% by weight of a digestible carbohydrate, and about 0.1 to about 1% by weight of a functional ingredient. The present invention also increases the lean body mass of companion animals, enhances satiety, decreases voluntary food intake and mitigates potential adverse medical risks associated with high protein diets.

[0016] Other objects, features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

BRIEF SUMMARY OF THE DRAWINGS

[0017] The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of specific embodiments presented herein:

FIG. 1 is a chart illustrating comparative percent body weight changes over time in dogs consuming the inventive diets versus control diets;

FIG. 2 is a chart illustrating the percent change in lean and fat mass over time;

FIG. 3 is a chart illustrating the blood urea nitrogen (BUN) levels of dogs consuming the inventive diets or control diets over time; and

FIG. 4 is a chart illustrating the blood urea nitrogen (BUN)/creatinine ratio levels in dogs consuming the inventive diets or control diets over time.

DETAILED DESCRIPTION OF THE INVENTION

DEFINITIONS

[0018] The term “functional ingredient” as used herein refers to a compound, naturally occurring or synthetic, that is included in a composition and effects a preventative and/or therapeutic response by modulating metabolism in a manner found to be specific to the compound.

[0019] A diacylglyceride is a lipid structurally characterized by a glycerol (a three carbon alcohol) backbone, two fatty acid chains and a phosphate group. By definition, a 1,2-diacylglyceride comprises fatty acid chains located at carbons 1 and 2 and, further, are characterized by a long hydrocarbon molecule such as unsaturated, saturated and conjugated hydrocarbons. 1,2-diacylglyceride is a precursor to phosphatidylcholine, phosphatidylethanolamine and phosphatidylinositol, which are indispensable components of biological membranes. In addition, 1,2-diacylglycerides are precursors to triglyceride biosynthesis and, therefore, is central to energy stores of organisms. However, 1,3-diacylglycerides are not metabolized to triglyceride and, thus, are not deposited as fat but rather, burned as energy. 1,3-diacylglyceride differs structurally from 1,2-diacylglycerides by having an acyl group at C-3 of the glycerol backbone rather than at C-2. Clinical investigations of obesity have included dietary consumption of diacylglycerol and indicated that diacylglycerol lowers serum triglyceride and cholesterol levels (Takasaka et al., 2000) and decreases body weight and regional fat deposition (Nagao et al., 2000). Rich natural sources of 1,3-diacylglycerides are vegetable oils, such as Econa oil. However, a synthetic 1,3-diacylglyceride is also contemplated. As used herein, the term “diacylglycerol” and, interchangeably, “diacylglyceride” refer to a 1,3-diacylglycerol molecule unless otherwise noted.

[0020] A compound, component or composition is said to be “acceptable” if its administration can be tolerated by a recipient mammal. Such a component is said

to be administered in an "effective amount" if the amount administered is physiologically significant. A component is physiologically significant if its presence results in technical change in the physiology of a recipient mammal. For example, in weight management of companion animals, an agent which slows, hinders, delays, completely treats the disease and/or symptoms of obesity, is considered effective.

[0021] By body composition, it is meant the total quality of lean, fat and bone in the body. By improved body composition, it is meant that the animal exhibit a greater percentage of lean tissue and a lower percentage of body fat energy intake in excess of that utilized for daily activities.

[0022] Current weight loss diets for dogs rely on severe calorie restriction and caloric dilution for effectiveness. The present invention discloses a high protein diet that includes a functional ingredient for promoting weight loss in obese dogs without utilizing severe calorie restriction or caloric dilution. The present invention is directed to a weight management system for domestic animals that provides for the optimization of an animal's body composition through dietary intervention and a process for producing a pet food product and a pet food product that provides for a comprehensive weight management system. The weight management system includes a pet food product that generally includes, on a dry matter basis, about 35 to about 70% by weight of a protein, about 4 to about 10% by weight of a fat, about 5 to about 25% by weight of a fiber, about 10 to about 35% by weight of a digestible carbohydrate, and about 0.1 to about 1 % by weight of a functional ingredient.

[0023] Feeding companion animals, such as a dog or cat, and alternatively obese dogs and cats, the pet food of the subject invention will help optimize the body composition of a domestic animal by modulating metabolism and building lean muscle mass. Feeding companion animals the pet food of the subject invention will also enhance the satiety and decrease voluntary food intake of the companion animal. Feeding companion animals the pet food of the subject invention will decrease blood urea nitrogen levels (BUN) and blood urea nitrogen (BUN)/creatinine ratio levels, thereby reducing the risk of kidney damage to the animal.

[0024] As is known to one skilled in the art, there are a variety of commonly known pet food products. In the area of cat and dog food, there is wet pet food, semi-moist pet food, dry pet food and pet treats and snacks. Drinks for pets are also available such as milk drinks for cats. Wet pet food generally has a moisture content above 65%. Semi-moist pet food typically has a moisture content between 20 - 65%

and can include humectants such as propylene glycol, potassium sorbate, and other ingredients to prevent microbial growth (bacteria and mold). Dry pet food (kibble) generally has a moisture content below 20% and its processing typically includes extruding, drying and/or baking in heat. Pet treats and snacks can typically be semi-moist chewable treats or snacks; dry treats or snacks in any number of forms; chewable bones; baked, extruded or stamped treats; confection treats/snacks; or other kinds of treats as is known to one skilled in the art.

[0025] A semi-moist pet food product generally includes ingredients such as cereal grains, meats, fats, vitamins, minerals and functional ingredients that are blended together, cooked and packaged. However, any semi-moist pet food formulation known to one skilled in the art can be used. For example, a pet food of the subject invention can be formed by adding about 35 to about 70% by weight of a protein, about 4 to about 10% by weight of a fat, about 5 to about 25% by weight of a fiber, about 10 to about 35% by weight of a digestible carbohydrate, and about 0.1 to about 1% by weight of a functional ingredient. Alternatively, the pet food can be formed by making a first mixture of about 35 to about 70% by weight of a protein, about 4 to about 10% by weight of a fat, about 5 to about 25% by weight of a fiber, and about 10 to about 35% by weight of a digestible carbohydrate. The functional ingredient is then added to the first mixture in about 0.1 to about 1% by weight.

[0026] In an example of a dry pet food, the ingredients generally include cereal grains, meats, poultry, fats, vitamins, minerals and other functional ingredients. The components are mixed and put through an extruder/cooker. Thereafter, the product is cut or shaped and dried. After drying, flavors, fats and other functional ingredients can be coated or sprayed onto the dried product. The spray used is of a kind that is known to one skilled in the art of producing dry pet food.

[0027] Although a composition and process for producing a semi-moist pet food product and a dry pet food product has been generally described above, it should be appreciated that any semi-moist pet food composition and process or dry pet food composition and process known to one skilled in the art can be used to produce the pet food product of the subject invention.

[0028] A wet pet food and pet treats/snacks are produced as is known to one skilled in the art depending upon the kind of wet pet food product and treat or snack desired. The procedure for preparing the pet food of the present invention depends upon the type of processing required to manufacture the wet pet food or treat/snack.

For example, in semi-moist treats/snacks, in which the processing temperature usually does not exceed 5 to 70 degrees C, some or all of the components are added to the treat during processing. However, if the processing temperature of the treat generally exceeds 70 degrees C and a component such as a functional ingredient displays temperature sensitivity, then the temperature-sensitive component is coated on the finished product.

[0029] In specific embodiments, the about 4 to about 10% by weight of fat can be provided by a fat that comprises essential long-chain fatty acids. This is particularly desirable in a pet food product for cats. Functional ingredients that modulate metabolism and build lean body mass include L-carnitine, conjugated linoleic acid and a diacylglyceride, and preferably include conjugated linoleic acid and diacylglyceride, and more preferably include a diacylglyceride. A non-limiting example of a source of a diacylglyceride is Econa oil. In a specific embodiment, the diacylglyceride is obtained from a vegetable oil having a diacylglyceride content of about 1% to about 85%. In a preferred specific embodiment, the diacylglyceride is obtained from a vegetable oil having at least about 5% diacylglyceride content.

[0030] A skilled artisan is aware that a pet food product further comprising vitamins, trace minerals and flavorings, is within the scope of the present invention, and is preferred to provide the animal with an entire daily diet to manage obesity and promote healthy living.

[0031] A process for producing the pet food of the subject invention includes the step of adding about 35 to about 70% by weight of a protein, about 4 to about 10% by weight of a fat, about 5 to about 25% by weight of a fiber, about 10 to about 35% by weight of a digestible carbohydrate and processing a first mixture. The first mixture is then combined with about 0.1 to about 1% by weight of a functional ingredient to provide a weight management system in which the functional ingredient modulates metabolism and builds lean muscle mass. Alternatively, the protein, fat, fiber, digestible carbohydrate and functional ingredient can be processed as one mixture.

[0032] The process of feeding the companion animal the inventive pet food product will promote comprehensive weight management in the companion animals, will increase the animal's lean muscle mass, and will enhance the satiety and decrease the voluntary food intake of the animal.

[0033] Thus, as described herein, the present invention provides a comprehensive approach to help optimize the body composition of a domestic animal. The invention targets (i) an induction in adipose (fat) metabolism, (ii) a minimization of muscle wasting that can occur from low protein, calorie-restricted diets and (iii) an increase in satiety and maintenance of palatability to reduce behavioral changes (i.e., begging) which lead to increased caloric consumption and non-compliance to a caloric restricted diet. This system reduces the total energy delivery, induces an increase in fat metabolism, and thus, leaves the pet satiated. This system also reduces the risk of kidney damage presented by high protein diets by decreasing BUN levels and BUN/creatinine ratio levels in the animal.

EXAMPLE

[0034] Five test diets (n = 10 obese dogs/diet) were tested for a 12 week period. The five diets included: (1) Control (28% protein); (2) Control + Conjugated Linoleic Acid (CLA); (3) Control + diacylglycerides (DAG); (4) High protein (50% protein); and (5) High protein + CLA. Dogs were fed at a slight caloric restriction (15% caloric restriction based on baseline caloric intake) to encourage weight loss. Lean body mass was determined by isotope ratio mass spectrometry (IRMS) in deuterium oxide (D₂O), and the fat mass was calculated by subtracting the lean body mass from body weight.

[0035] As illustrated in the chart of FIG. 1, the results showed a significantly greater weight loss in the dogs fed the high protein diets as compared to the control diet and the other test compound diets, with or without the functional ingredient CLA.

[0036] The observed weight loss of the dogs on all five diets is due to a significant loss of fat mass (FIG. 2) while sparing lean body mass. The dogs on the following diets: Control + Conjugated Linoleic Acid (CLA), Control + diacylglycerides (DAG), High protein (50% protein), and (5) High protein + CLA, experienced an increase in lean body mass. In contrast, the dogs on the Control diet demonstrated a slight decrease in lean body mass. Interestingly, the effect of DAG alone on fat mass and lean body mass indicates its importance as a functional ingredient in a weight management system. Comparing the two high protein diets demonstrates that the effect of consuming high protein is stronger than the effect observed with CLA alone on both fat and lean body mass. From these results, it is

clear that a comprehensive weight management system including high protein, conjugated fatty acids and 1,3-diacylglycerides is effective in promoting an increase in lean body mass and a decrease in fat mass.

[0037] BUN levels are a direct measure of protein consumption. Dogs fed the HPLC (high protein, low carbohydrate) diet expectedly demonstrated increased BUN levels (FIG. 3) and increased BUN/creatinine ratio levels (FIG.4). However, the high protein diets comprising conjugated linoleic acid (HPLC + CLA) or a 1,3-diacylglyceride (Econa) maintained normal BUN levels as compared to the Control dieter levels over the 12 week test period. The designations "a", "b" and "c" indicate significant differences between the designated groups ($p > 0.05$) at the time the blood was taken. Each diet afforded normal BUN levels, with or without the correction for creatinine, for the first half of the testing period. After 6 weeks, dogs fed the HPLC diet demonstrated above normal and significantly different BUN/creatinine ratio levels (FIG. 4) as compared to the CLA, HPLC + CLA and Econa dieters. Similarly, direct measurement of BUN levels yielded above normal and statistically different levels as compared to the CLA, HPLC + CLA and Econa fed dogs (FIG. 3).

[0038] This unexpected effect of the inventive diets on protein metabolism indicates that potential medical risks associated with high protein diets are neutralized by co-consumption of the functional ingredients. The reduced risks of renal (*e.g.* kidney) damage and failure by consumption of the inventive diets is a substantial metabolic improvement in efforts to prevent and treat obese animals.

[0039] A common misconception in treating and preventing obesity in companion animals is that a drastic reduction in food intake is required. When this occurs, the animals often scavenge and beg for food because of the constant hunger sensation. As a result of hunger sensations, the animal finds additional food or pet owners feed the animal in order to stop the begging, with the result of no weight reduction. In prior art methods, for weight reduction to occur, the animal's food intake must be decreased for a sustained and regular period of time and the animal must be inhibited from constant scavenging and begging, which increases the food intake. Most pet owners fail in the treatment and prevention of obesity in their pets because they are unable to keep the animal's food intake at a decreased level for extended periods of time, and they are unable to prevent their animals from scavenging and begging.

20221016045001

[0040] The novel weight management system provides a comprehensive approach to help optimize the body composition of a domestic animal through dietary intervention without the side effects associated with prior diets. The present invention targets (i) an induction in adipose (fat) metabolism, (ii) an increase in satiety and maintenance of palatability to reduce behavioral changes (i.e., begging) which lead to increased caloric consumption, and (iii) a minimization of muscle wasting that can occur from low protein, calorie-restricted diets. This weight management system reduces the total energy delivery, induces an increase in fat metabolism, and thus, leaves the pet satiated. Further, this weight management system mitigates potential adverse effects associated with consumption of high protein diets.

[0041] Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

References

[0042] The following references, to the extent that they provide exemplary procedural or other details supplementary to those set forth herein, are specifically incorporated herein by reference:

U.S. Patent No. 3,830,931 issued August 20, 1974.

U.S. Patent No. 3,968,241 issued July 6, 1976.

U.S. Patent No. 3,810,994 issued May 14, 1974.

U.S. Patent No. 6,071,544 issued June 6, 2000.

U.S. Patent No. 6,204,291 issued March 20, 2001.

U.S. Patent 3,810,994 issued May 14, 1974.

U.S. Patent 4,255,449 issued March 10, 1981.

U.S. Patent No. 4,737,364 issued April 12, 1988.

U.S. Patent 5,141,755 issued August 25, 1992.

WO 00/51443, publication date September 8, 2000.

EP 965278 A1, publication date December 12, 1999.

Appleton, D.J., Rand, J.S., Sunvold, G.D. "Feline obesity: pathogenesis and implications for the risk of diabetes" in Recent Advances in Canine and Feline Nutrition. Vol. III: 2000 IAMS Nutrition Symposium Proceedings. pp. 81-90.

Nobels, F, van Gaal, L., de Leeuw, I. *Netherlands Journal of Medicine*, 35: 295-302 (1989).

Yalkowsky, S.H., *Pharmaceutical Society*, 59(6), 798 (1970).

Sunvold, G.D. "The role of novel nutrients in managing obesity" in Recent Advances in Canine and Feline Nutrition. Vol. III: 2000 IAMS Nutrition Symposium Proceedings. pp. 123-133.

Bouchard, G.F., Sunvold, G.D. "Effect of dietary carbohydrate source on postprandial plasma glucose and insulin concentration in cats" in Recent Advances in Canine and Feline Nutrition. Vol. III: 2000 IAMS Nutrition Symposium Proceedings. pp. 91-101.

Hara, K. et al. "Dietary Diacylglycerol-Dependent Reduction in Serum Triacylglycerol Concentration in Rats" *Ann. Nutr. Metab.*, 37, 185-191 (1993).

Watanabe H., et al. Nutritional characteristics of diacylglycerols in rats" *J. Japan Oil Chem. Soc.*, 46, 301-307 (1997).

Nagao, T. et al. "Dietary Diacylglycerol suppresses accumulation of body fat compared to triacylglycerol in men in a double-blind controlled trial" *J. Nutr.*, 130, 792-797 (2000).